

HEALTHCARE TECHNOLOGY COMMERCIALIZATION: MULTIPLE PATHWAYS OF ACTIVITY



Translational Research → Technology/Product Development → Production and Operation

Research & Development	Preliminary Data	Prototype ↕ Design Preclinical	Physician Sponsored Clinical Trials	Clinical Trials Phases I, II, III	Product Configuration	Post-market Modifications
Intellectual Property	Invention Disclosure	IP Analysis	Freedom to Practice	Patent Filing	Patent Protection	Patent Extension Patent Defense
Business Development	Clinical Needs Assessment	Commercialization Plan	Start up License	Business Plan Tech Transfer	Follow-on Funding	
Regulatory	GLP Design controls	IRB	IND/IDE	BLA/NDA PMA/510k	QSR ISO	Labeling Promotion
Marketing	Market Research	Education	Promotion	Market Approval	Sales	Adoption Distribution
Manufacturing & Production	Materials & Components	Processes Tooling	GMP	Pilot → Scale up → Full	Product Improvements	
Coverage & Reimbursement	Competitive Pricing assessment	Reimbursement & Coverage plan	Economic Outcomes analysis	CMS HCPCS application	DRG Coding	

Adapted from a slide by C Goodman, The Lewin Group

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